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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,811	05/14/2001	Robert E. Reiter	30435.69USD2	9472

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MANDEL & ADRIANO
55 SOUTH LAKE AVENUE
SUITE 410
PASADENA, CA 91101

EXAMINER	
HELMS, LARRY RONALD	
ART UNIT	**PAPER NUMBER**
1642	20

DATE MAILED: 10/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/854,811	REITER ET AL.	
	Examiner	Art Unit	
	Larry R. Helms	1642	

-- The MAILING DATE of this communicati n appears on the cover sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 September 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *53,58-74 and 77-97* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *53,58-74 and 77-97* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 54-57, 75-76 have been canceled.

Claims 77-97 have been added.

2. Claims 53, 58-74, 77-97 are pending and under examination.

3. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.

4. The following Office Action contains NEW GROUNDS of rejection.

5. It is acknowledged that the substitute specification has been entered.

Rejections Withdrawn

6. The rejection of claims 53, 58-74 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments to the claims.

7. The rejection of claims 53, 58-74 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in view of the amendments to the claims.

8. The rejection of claim 73 under 35 U.S.C. 103(a) as being unpatentable over Au-Young (U.S. Patent 5,856,136, filed 7/96) and further in view of Spitler (U.S. Patent 5,738,867, filed 6/95) is withdrawn in view of the amendments to the claim.

9. The rejection of claim 73 under 35 U.S.C. 103(a) as being unpatentable over Billing-Medel et al (WO 98/51805, published 11/98, IDS #8) and further in view of Spitler (U.S. Patent 5,738,867, filed 6/95) is withdrawn in view of the amendment to the claim.

Response to Arguments

10. The rejection of claims 53, 58-73, and newly added claims 77-97 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inducing an immune response against the protein of SEQ ID NO:2 in a human cancer patient that expresses the protein of SEQ ID NO:2 or cells that express SEQ ID NO:2, wherein the method comprises administration of residues 1 to 123 of SEQ ID NO:2, does not reasonably provide enablement for a method of inducing an immune response against just any antigen in just any subject by administration of just any portion of SEQ ID NO:2 or a method of inducing an anti-tumor response in any subject with just any fragment of SEQ ID NO:2 . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims is maintained and made again.

The response filed 7/21/03 has been carefully considured but is deemed not to be persuasive. The response states that "cancer is not an element in any claims in this matter" (see page 13 of response). In response to this argument, claims 53, 58-73 specifically require a cancer patient and as such the immune response is directed to the cancer or eradicating the cancer. Therefore, the administration of a portion of SEQ ID NO:2 is to induce an immune response against the cancer, i.e. a cancer vaccine (in addition see arguments in 103 rejection on page 51 bottom of page). In addition newly added claim 77 comprises administration of dendridic cells which would only be applied to cancer patients as suggested in the specification at page 71 in the substitute specification. The response further states that the Examiner has inconsistencies in that he uses Spitler in the 103 and in the 112 first rejections (see page 13 of the response). In response to this argument, two different Spitler references were used and the art rejection is directed to what applicants are enabled for and as such there is no inconsistencies. The response further states that Spitler and Ezzell are both eight years old and do not reflect the state of the art in "tumor vaccines" now or at the time of filling and none the less the references are not relevant because the claims are directed to methods of inducing an immune response (see page 13 of response). In response to this argument, both references reflect the state of the art because cancer vaccines are unpredictable as cited by the references and the references are relevant because as stated above claims 53, 58-73 encompass a cancer vaccine. In addition the art teaches only using the entire protein not fragments or portions thereof. In addition, the response does not address the unpredictability of administrating just any fragment or portion of

SEQ ID NO:2 for inducing a tumor immune response. The claims encompass administering fragments of SEQ ID NO:2 and it is well known that not every fragment of a protein can be used to produce antibodies or produce an anti-tumor response that is encompassed in the claims. While an antibody can be made to any fragment of a protein not every fragment would produce an immune response that would result in an anti-tumor response. Due to the location of the fragment in the properly folded protein only those that would be recognized on the surface of the protein could be used for anti-tumor responses. Newly added claims 78-97 are included in this rejection because it is not clear if the immune response is directed to SEQ ID NO:2 or some other protein (see 112 second rejection below) and the specification only enables an immune response to SEQ ID NO:2 in sheep, rat, dog, cat, pig, horse or mouse, not humans because although claims 78-97 do not recite a cancer vaccine the claims encompass and are broadly interpreted to be such because the subject can have cancer and the specification does not teach an immune response in humans or in humans with cancer. The immune response in a human would broadly read on cancer vaccines because SEQ ID NO:2 is only expressed in human cancer.

11. The rejection of claims 53, 74, and newly added claims 77-81, 97 under 35 U.S.C. 103(a) as being unpatentable over Au-Young (U.S. Patent 5,856,136, filed 7/96) and further in view of Spitler (U.S. Patent 5,738,867, filed 6/95) is maintained.

The response filed 7/21/03 has been carefully considured but is deemed not to be persuasive. The response states several pages of legal standards and the

standards of 112 first enablement and written description (see pages 15-24). In response to this the examiner is well aware of the legal standards. The response further states that the invention is not obvious over the cited art and Au-Young teaches multiple assemblies that were from overlapping transcripts from normal uterine and bladder tumor and the attached declaration of Dr. Kanner gives reasons why Au-Young is deficient in the SCAH-2 disclosure (see pages 24-34). The response and the declaration have been carefully considured but are deemed not to be persuasive. To summarize the arguments are as follows:

Au-Young did not posses a gene or protein or antibodies that bind to such and nowhere in Au-Young is there any disclosure that the SCAH-2 excited in any cell and it appears that the response is directed to enablement and written description and it is hindsight in view of applicants discovery of PSCA and this is not how the obviousness of PSCA should be viewed (see pages 24-34). In response to these arguments, Au-Young teaches the protein in bladder cancer and that SEQ IS NO:2 is the protein and Au-Young was in possession of the protein as evidenced by SEQ ID NO:2 and Figure 3 which includes the open reading frame of SCAH-2. In response to the enablement a US Patent is presumed to be valid and enabled. Au-Young described SEQ ID NO:2 and its association in bladder cancer. In response to the hindsight argument, HINDSIGHT REPLY.

The response and the declaration then address six assumptions that underlie the rejection (see page 35-51). It is noted that the response only states five Assumptions

and the declaration addresses six. The response and the declaration of Dr. Kanner has been carefully considured but is deemed not to be persuasive.

The first assumption (all assumptions taken from the declaration) is that Au-Young disclosed a nucleic acid sequence that occurs in nature. The response and the declaration state that Au-Young only discloses a hypothetical gene. In response to this argument, the SCAH-2 sequence was disclosed and an open reading frame described (See SEQ ID NO:2 and Figure 3).

The second assumption is that the protein was truly encoded by the nucleic acid and that no protein was ever documented. In response to this again the protein of SEQ ID NO:2 and Figure 3 is documented as being SCAH-2.

The third assumption is that Au-Young had the actual sequence and in fact it was not clear what sequence Au-Young had. In response to this argument, again the protein of SEQ ID NO:2 and Figure 3 is documented as being SCAH-2.

The fourth assumption is that Au-Young had a particular reading frame when in fact no amino acid sequence in nature was ever documented. In response to this argument, again the protein of SEQ ID NO:2 and Figure 3 is documented as being SCAH-2.

The fifth assumption is that antibodies could be raised to SCAH-2 when in fact none were. In response to this applicants are directed to In re Sivaramakrishnan, 213 USPQ 441 (CCPA 1982) which clearly discusses that a reference that may not have actually reduced specific mixture to practice has no bearing on whether the mixture is

described in printed publication. SCAH-2 is disclosed and at the time of the filing of the application producing antibodies to proteins was routine.

The sixth assumption is that every antibody was in fact raised and in fact no antibodies were raised. In response to this argument, see above and the claims are directed to an immune response not to producing antibodies per se.

The response further states that the Spitler reference is prophetic and does not indicate that the TAA-liposomes actually induce an immune response let alone an anti-tumor response (see page 51 of response). In response to this argument, the claims in the patent of Spitler are directed to an antitumor vaccine with the entire antigen. The response further states that Au-Young failed to teach any use for SCAH-2 leading to no motivation to use it to regulate an immune response or to replace TAA of Spitler woth SCAH-2 (see page 52-53 of response). In response to this argument, Au-Young teach SCAH-2 is associated with bladder tumor and the protein can be used for treatment and prevention of diseases (see column 4, lines 16-31) and Spitler teach using any tumor antigen and SCAH-2 is associated with tumors and as such it would be obvious to use SCAH-2 in the method of Spitler.

The following are NEW GROUNDS of rejection

12. Claims 78-97 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 78-97 are indefinite for reciting "a method of inducing an immune response in a mammalian subject" in claim 78 because the exact meaning of the phrase is not clear. What is the immune response directed against? Is the immune response directed against SEQ ID NO:2 or some other antigen?

Conclusion

13. No claim is allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, PhD, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

16. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879

LARRY R. HELMS, PH.D
PRIMARY EXAMINER